On March 25 and 26, the U.S. Food and Drug Administration (FDA) held a public hearing to gather suggestions for potential improvements to its system for approving over-the-counter (OTC) drugs. FDA announced the hearing in late February, explaining in the Federal Register that the current approval process does not always allow the agency to respond quickly as new safety information about approved drugs emerges, or as innovations relating to approved drugs develop.

FDA currently regulates OTC drugs through a monograph system, where each active drug ingredient is the subject of a monograph setting forth the manufacturing standards for that drug. Individual manufacturers do not have to apply for approval each time they want to market a new product. Instead, they can follow the FDA’s monograph for the active drug ingredients in the product. As long as the manufacturer’s OTC drug product conforms to the monograph, FDA will consider the drug “generally recognized as safe and effective.” Currently, to develop a monograph, FDA must go through a three-step
review process, which includes publication of an advance notice of proposed rulemaking, followed by a tentative final monograph, followed by a final monograph.

At the March hearing, Center for Drug Evaluation and Research (CDER) director Dr. Janet Woodcock explained that although the monograph system has been effective in many respects, its limitations have become increasingly apparent in recent years. The monograph system has made it difficult for FDA to quickly incorporate new information, such as information about pediatric dosing, into final monographs. It has also failed to accommodate innovation, such as new dosage forms like spray sunscreen. In addition, under this system, progress on monographs sometimes stalls for decades. For example, FDA first issued tentative monographs covering various topical antimicrobial drug products in 1974. Revisions have been made to the monographs since then, but the monographs remain in tentative form today.

Speakers at the March hearing included representatives of industry groups the Consumer Healthcare Products Association and the Personal Care Products Council; manufacturers Novartis Consumer Health, Proctor & Gamble, CB Fleet, and Johnson & Johnson; and NGOs the Gerontological Society of America, Independent Cosmetic Manufacturing and Distribution, the Drug Safety Project for the PEW Charitable Trusts, the American Academy of Pediatrics, and the Fluoride Action Network. There was also testimony from members of academia.

There was broad support among the speakers for maintaining the current monograph system. Several speakers recommended that, regardless of other changes FDA may implement, its first priority should be to finalize all monographs that are currently in tentative form. One speaker suggested that finalization should be prioritized according to the following categories: ingested drugs with dose restrictions, topical drugs with dose restrictions, and topical drugs without dose restrictions.

Speakers offered the following suggestions for improving the monograph process itself:

Public/private partnership. One speaker suggested that FDA involve industry in a public/private partnership that would provide resources to move the monograph process forward. The partnership would prioritize the remaining outstanding monographs. It would then ensure that existing data are collected and assessed, help identify and evaluate gaps in data, and make a recommendation as to whether the monograph should be changed or finalized as is. The partnership’s recommendation would not replace public comment but would help expedite the process. The partnership could also help evaluate the monograph system to find areas for improvement going forward.

Transparency. Several speakers asked FDA to be more transparent in the monograph process. Some wanted FDA to set deadlines for finishing the monographs currently in tentative form. Other suggested that FDA hold a public meeting to explain the current process in detail so that industry and other stakeholders could understand any current obstacles to completing monographs. There was also a recommendation that FDA communicate more frequently with interested parties during the rulemaking process.

Accountability. In addition to increased transparency, some speakers urged steps to make FDA more accountable in the monograph process. Some suggested transferring OTC drug review from FDA’s New Drug Division to the Office of Regulatory Policy. One speaker suggested requiring a yearly report from the commissioner on the status of OTC drug review, with a yearly advisory committee meeting. Former FDA chief counsel Peter Barton Hutt urged the agency to allocate more funding to
the OTC drug review process, designate a pharmacist to head the process, and give that person the authority to require prompt decisions by the review divisions and to set compliance policy.

Beyond proposals for finalizing the outstanding monographs, speakers had a range of suggestions relating to using mechanisms outside the monograph system for improving the flexibility of the FDA’s regulation of OTC drugs. Suggestions outside the monograph system included:

Guidances. Several speakers suggested that FDA use guidances to set policy where the formal rulemaking process does not allow for prompt action. A few speakers suggested that FDA use guidances as a way of allowing new dosage forms. The guidances could designate the types of data that manufacturers would need to have on file in order to market new dosage forms. Hutt emphasized that FDA has a range of non-rulemaking tools, including guidances, Federal Register notices, and enforcement letters, to address immediate situations that may require faster action than a formal rulemaking.

Enforcement discretion. Some speakers said that FDA should exercise enforcement discretion to allow manufacturers to add new labeling information before the information could be incorporated into a final monograph. One speaker suggested an amnesty consolidation process. In this process, all companies would reveal to FDA any modified dosage forms for drugs that are in tentative final monographs or final monographs, and FDA would use enforcement discretion to allow these to remain on the market until it could more fully evaluate the safety and efficacy of the new forms.

Application process. Several speakers advocated for an application process that would allow manufacturers to request approval for changes to labeling or other changes. The application would not be as detailed as a new drug application. One speaker suggested that for topical non-dosage products in particular, such as sunscreen, FDA could make an initial determination whether the application contained sufficient information concerning the safety and effectiveness of the product and the extent of use abroad, then issue a notice of proposed rulemaking to include the product in the relevant monograph while allowing marketing on an interim basis.

Notification process. One speaker recommended that FDA allow manufacturers to update their drug facts labeling upon a notification to FDA. Alternatively, FDA could create a label area separate from the drug facts box where manufacturers could voluntarily add safety information, also upon notification to FDA. The separate safety information could then be evaluated to determine if it should move into the drug facts box.

Following the hearing, FDA received written comments on the OTC drug process. The comment period ended last week. It is now up to the FDA to consider the comments and determine the next steps.

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